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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,168	12/14/2001	Hsi Liu	6395-61666	9437

7590 03/02/2004

KLARQUIST SPARKMAN, LLP
One World Trade Center
Suite 1600
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,168	LIU ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-16,27,28,30 and 31* is/are pending in the application.

4a) Of the above claim(s) *4, 8-10 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,11-16,28,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *01/25/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed November 24, 2003. Claims 1-2, 11-12, 16, 28 and 30-31 have been amended. Claims 3, 17-26, 29 and 32-36 have been cancelled.

Restriction/Election

2. In response to Applicants argument concerning the restriction requiring Applicant to elect one single sequence, SEO Nos: 2, 4, 6, 15, 17, 18, 20, 22, 24 and 26 are structurally different. Although the claimed sequences are a part of a genus, each sequence is structurally distinct each from the other will require a separated search. Therefore, the restriction requirement and election of species is deemed proper and made final.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. The rejection following rejections are withdrawn in view of Applicant's amendment and response:

a) Objection to the specification, page 2, paragraph 2 of the previous Office action.

b) Rejection of claims 1-3, 5-7, 11-16, 28 and 30-31 under 35 U.S.C., 112, first paragraph, pages 3-6, paragraph 3, of the previous Office action.

c) Rejection of claims 1-3, 5-7, 11-16, 28 and 30-31 under 35 U.S.C., 112, second paragraph, page 6, paragraph 4, of the previous Office action.

d) Rejection of claims 1-3, 5-7, 11-16 and 30-31 under 35 U.S.C., 102(b), pages 7-8, paragraph 5, of the previous Office action.

e) Rejection of claims 1-3, 5-7, 11-16 and 30-31 under 35 U.S.C., 102(b), pages 9-10, paragraph 6, of the previous Office action.

f) Rejection of claims 1-3, 5-7, 11-16 and 30-31 under 35 U.S.C., 102(b), pages 10-11, paragraph 7, of the previous Office action.

g) Rejection of claim 28 under 35 U.S.C., 103(a), page 12, paragraph 8, of the previous Office action.

h) Rejection of claim 28 under 35 U.S.C., 103(a), page 13, paragraph 9, of the previous Office action.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-7, 11-16 and 30-31 are rejected under 35 U.S.C. 102(b) as anticipated by Norgard et al *(Journal of Clinical Microbiology, October 1984, p. 711-717).*

Claims 1-2, 5-6, 11-16 and 30-31 are drawn to a method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample comprising contacting an isolated immunogenic *Treponema pallidum* acidic repeat protein or one or more isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein with an antibody-containing biological sample wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence $EVEDX_1PX_2VVEPASX_3X_4EGGER$, wherein X_1 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H; and detecting formation of a complex between the immunogenic protein or peptide and the antibody, wherein the presence of the complex indicated the presence of *Treponema pallidum* or anti-treponemal antibodies in the biological sample.

Norgard et al teach a method of detecting *anti*-Treponema monoclonal antibodies in various body fluids in the diagnosis of syphilis (see the Abstract). Norgard et al teach that the anti-*T. pallidum* antibodies used in the assay were affinity purified (i.e. isolated from clone) (page 712). The sequence of the *T. pallidum* peptide, for example SEQ ID NO: 15 would be inherent in the teachings of the prior art. Norgard et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to

show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 1-2, 5-7, 11-16 and 30-31 are rejected under 35 U.S.C. 102(b) as anticipated by Hunter et al *(Journal of Clinical Microbiology, September 1982,p. 483-486).*

Claims 1-2, 5-6, 11-16 and 30-31 are drawn to a method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample comprising contacting an isolated immunogenic *Treponema pallidum* acidic repeat protein or one or more isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein with an antibody-containing biological sample wherein the acidic repeat protein or the isolated immunogenic *Treponema pallidum* peptide(s) of the acidic repeat protein comprises the amino acid sequence $EVEDX_1PX_2VVEPASX_3X_4EGGER$, wherein X_1 is A or V; X_2 is K or G; X_3 is E or G; and X_4 is R or H; and detecting formation of a complex between the immunogenic protein or peptide and the antibody, wherein the presence of the complex indicated the presence of *Treponema pallidum* or anti-treponemal antibodies in the biological sample.

Hunter et al teach a method of detecting syphilis in sera samples using a desoxycholated-extracted treponemal antigen (i.e. isolated) in an enzyme-linked immunosorbent assay (see the Title and the Abstract). The sequence of the *T.*

pallidum peptide, for example SEQ ID NO: 15 would be inherent in the teachings of the prior art. Hunter et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as unpatentable over Hunter et al *(Journal of Clinical Microbiology, September 1982,p. 483-486).*

Claim 28 is drawn to a kit for detecting *T. pallidum* in a biological sample using the method of claim 1, comprising an isolated acidic repeat protein or one or more isolated, immunogenic *Treponema pallidum* peptide of the acidic repeat protein and instructions for carrying out the method of claim 1.

Hunter et al teach a desoxycholated-extracted treponemal antigen (i.e. isolated) used in an enzyme-linked immunosorbent assay to detect *T. pallidum* in a biological

sample (see the Title and the Abstract). In re Venezia 189 USPQ 49 (CCPA 1976), held that kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. It would be obvious to use the desoxycholated-extracted treponemal antigen used in an immunoassay of the prior art in a diagnostic kit to detect *T. pallidum* in a biological sample. It would also be obvious to include the instructions for using the kit, because it is well known in the art to include instructions with diagnostic kits.

It should be noted that the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. It is also noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the

prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571)272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
February 11, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600